UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	

UNITED STATES' RESPONSE TO DEFENDANT ABBOTT LABORATORIES INC.'S OBJECTIONS TO AUGUST 13, 2007 ORDER BY MAGISTRATE JUDGE BOWLER

Defendant Abbott Laboratories Inc.'s Objections to Magistrate Judge Bowler's August 13, 2007 Order rest on a completely erroneous premise. That premise is Abbott's assertion that the United States has placed all of its internal deliberations concerning drug reimbursement at issue in this case simply by suing Abbott. This case, however, is not about the Government's drug reimbursement systems, the views of individual federal employees about those systems, or the underlying merits of AWP as a reimbursement benchmark. This case is about Abbott's conduct – namely, Abbott's deliberate creation of spreads on certain drugs, its marketing of these spreads to providers, the resultant submission of false claims, and the company's *scienter* in doing so. In other words, this case is about Abbott's abuse of the relevant government reimbursement systems.

The faulty premise outlined above infects each of Abbott's arguments in its objections to the Magistrate Judge's Order. Given the lack of evidentiary value of documents reflecting

macro-level governmental deliberations about drug reimbursement issues, there is certainly no wholesale waiver of the deliberative process privilege with respect to these documents. Furthermore, any weighing of Abbott's need for the documents against the government's interests in protecting its deliberative processes tips heavily in the United States' favor when one considers the fundamental irrelevance of the documents to the specific claims and defenses in this case. Finally, Abbott's arguments concerning the relevance of generalized governmental deliberations to the United States' causes of action would have significant and negative ramifications for both the status of the deliberative process privilege and future False Claims Act (FCA) litigation. For these reasons, this Court should wholly reject Abbott's objections to Magistrate judge Bowler's April 13, 2007 Order.

STANDARD OF REVIEW

Abbott's Objections fail to note the pertinent standard of review. Pursuant to 28 U.S.C. § 636(b)(1)(A), a Magistrate Judge's discovery ruling will be set aside if it is "clearly erroneous or contrary to law." *See In re Administrative Subpoena Blue Cross Blue Shield of Massachusetts*, 400 F.Supp.2d 386, 388 (D. Mass. 2005). Abbott asks this Court to hold that Magistrate Judge Bowler clearly erred in holding that the deliberative process privilege applies to *any* of the documents on the United States' privilege logs, and also to hold that Magistrate Judge Bowler clearly erred by not issuing a prospective ruling barring the United States from asserting the privilege at all in this case. In the alternative, Abbott contends that Magistrate Judge Bowler clearly erred by not holding that Abbott's need for the documents outweighs the government's clear interest in protection of its deliberative processes. As is discussed below, these requests lack a substantial basis in the case law, and should be denied.

ARGUMENT

I. The Documents on the Privilege Logs are of Minimal Relevance to the Claims and Defenses in this Case

Abbott's Objections to the Magistrate Judge's Order depend almost entirely on the notion that the specific allegations regarding Abbott's abuse of state and federal reimbursement systems in the United States' Complaint place all of the government's internal deliberative communications concerning drug reimbursement at issue in this litigation. Abbott contends this case turns on why the Government designed or continued to use drug reimbursement systems that relied on AWP, despite knowing of flaws in that reimbursement benchmark. In other words, Abbott's defense appears to consist of blaming the government for having allowed Abbott's conduct to happen.

The government's case, however, is about Abbott's conduct – specifically, about Abbott's practice of reporting inflated prices to third-party compendia, and Abbott's *scienter* in reporting those fraudulent prices. An examination of the specific causes of action the United States has brought against Abbott make this point clear, and illustrate the lack of relevance of documents such as those on the government's privilege logs to the claims and defenses in this case.

The Government's First Amended Complaint includes two FCA counts against Abbott, as well as a common-law fraud count. Abbott contends that, under these causes of action, "to prevail, the government must show that it was misled or deceived about the prices reported in the compendia for the Subject Drugs. By the same token, if Abbott proves the Government was not

misled about the Subject Drugs, Abbott must prevail in this case." *Def's Objections to Magistrate Judge Bowler's August 13, 2007 Order,* Docket No.*4698*, at 9-10.

Abbott's statement is fundamentally incorrect, and misconstrues the elements of the government's causes of action. The government does not need to prove it was "misled or deceived" in order to prove its FCA claims. "Government knowledge," as such, is simply not a defense to an FCA action. Government knowledge -- no matter how extensive -- of the falsity of a claim or statement, standing alone, does not defeat a claim under the FCA. *See Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d at 534-35 (holding that 1986 amendments to FCA make clear that government knowledge of a contractor's wrongdoing is not an automatic defense); *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("[t]hat the relevant government officials know of the falsity is not in itself a defense")*; United States v. Ehrlich*, 643 F.2d 634, 638-39 (9th Cir. 1981). This follows from the incontestable fact that the focus of the FCA is on the *defendant's* knowledge of falsehood, not on the government's knowledge, a fact that can be ascertained from a review of the statute's plain language. *See* 31 U.S.C. § 3729(a), (b). The statute says nothing whatsoever about the government's knowledge.

Government knowledge is relevant solely on the issue of the *defendant's* scienter, inasmuch as the defendant may have an argument that he or she has not "knowingly" submitted a false claim if the government knew of and approved of the defendants' conduct. *See, e.g., United States ex rel. Oliver v. Parsons Co.,* 195 F.3d 457, 464-65 (9th Cir. 1999) ("'[i]nnocent mistakes' and 'negligence' are not offenses under the Act"; *United States ex rel. Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1991). The cases correctly recognize that the central question is whether the defendant knew that it caused false claims to be submitted, and that the

existence of government knowledge of falsity does not necessarily or even generally vitiate the existence of the defendant's knowledge.

In the instant case, the documents listed on the attached privilege logs have never been shared with anyone outside of the Government and its agents (with the exception of the two privileged documents the United States filed under seal with this Court as exhibits to its objections to Magistrate Judge Bowler's Order), and thus have never been shared with Abbott. Indeed, none of the documents on any of the logs refer to any communications between the government and Abbott concerning drug reimbursement, a fact which could be confirmed by the Court through an *in camera* review. Given these facts, Abbott cannot make a credible argument that the deliberative processes contained in the documents on the attached privilege logs could possibly be construed to undermine *Abbott's* scienter under the FCA. At the very least, the burden is on Abbott to establish that the documents on the United States' privilege logs could be relevant to its scienter under the FCA.

Apparently recognizing the difficulty of arguing that its scienter was undermined through non-public documents, Abbott argues that the documents on the log are relevant to other elements or components of the government's causes of action, such as materiality, causation, or reliance. These arguments are similarly flawed. While the FCA contains no separate materiality element, the pertinent liability provisions have long been held to require proof of a logical connection, between a defendant's false statement and a federal payment decision. In short, "a false statement is material if it has a natural tendency to influence, or is capable of influencing, the decision of the decision making body to which it was addressed." *See Kungys v. United States*, 485 U.S. 759, 770 (1988). *See also United States v. Southland Management Corp.*, 326

F.3d 669, 679 (5th Cir. 2003) (en banc) (Jones, J., specially concurring). This is often an issue in FCA cases where a contractor or grantee is alleged to have violated a contractual or regulatory provision that may not bear a nexus to the Government's decision to pay a claim at all, or to pay a claim at a particular amount. Causation is relevant to both the United States' FCA and common-law fraud counts. Justifiable reliance is not an element of the FCA, but is an element of the government's common-law fraud count.

Abbott does not and cannot explain how the documents it seeks from the United States' privilege logs are relevant to these issues. Indeed, these issues are unrelated to the documents contained on the Government's privilege logs, because materiality, causation, and reliance were established by operation of the reimbursement systems that were in place. To the extent that the United States was reimbursing claims for Abbott's drugs at an amount tied to AWP under the pertinent Medicare and Medicaid statutory and regulatory regimes, the AWPs that Abbott reported obviously affected the government's reimbursement amounts, and were thus *material* to the government's reimbursement of the claim. Put another way, given the system that was in place, if Abbott had reported accurate prices, as opposed to AWPs one thousand percent higher than its acquisition costs, this would have had an effect on the amount the government reimbursed providers for Abbott's drugs.

Causation and reliance are similarly incontestable based upon the operation of the reimbursement systems in place. Abbott's reported prices undoubtedly caused the Medicare and Medicaid programs to reimburse Abbott drugs at an amount the government alleges was inflated. The causal nexus between Abbott's reported AWPs and the government's reimbursement amounts was established through operation of the system, in which providers submitted claims

for payment based upon prices reported by manufacturers. *See, e.g. Memorandum and Order, State of California ex rel. Ven-A-Care v. Abbott Laboratories Inc.,et al,* Docket No. 4056 at 19 ("[a]s the defendants knew that MediCal calculated its payments based upon prices reported to [the compendia], it is reasonable and foreseeable that an overpayment by the state would necessarily result from such false reporting by doctors."). With respect to justifiable reliance, the entire concept presupposes some ability on the part of the victim to not rely. Reliance under the circumstances at issue in this case was established by the statutes and regulations tying reimbursement to AWP, not by some specific agency decision that Abbott's customers deserved to be reimbursed based on whatever AWP Abbott chose to report, regardless of its truth or falsity. Abbott cannot seriously contend that there is a legitimate debate regarding the government's reliance on its false statements – Abbott knew full well that the government would be reimbursing providers at an amount tied to its own price reporting. *See*, *e.g.*, *Findings of Fact and Conclusions of Law*, June 21, 2007, Docket No. 4366 at 144-145 ("[m]oreover, defendants knew that neither the government nor the [third-party payors] could do much to change the AWP reimbursement benchmark because they were locked in to the nationwide reimbursement scheme established by statute or contract."). Under the system that was in place at the time, Abbott cannot establish that its price reporting was immaterial to the government's reimbursement actions in this case, and nothing in the documents on the United States' privilege logs goes to this issue.

Furthermore, few of the documents on the relevant privilege logs contain any reference whatsoever to Abbott or to Abbott drugs. Out of the more than 650 documents on the three logs, there are approximately 41 documents that mention Abbott or the subject drugs at issue in this

litigation. The United States has argued in its own objections to the August 13, 2007 Order that simple references to Abbott or a subject drug in a documents are hardly a proxy for relevance in this case. However, it is clear that documents that contain no reference to Abbott or the subject drugs are of dubious relevance to the instant case. *See Pretrial Conference Transcript*, April 11, 2007, Ex. 1, at 21 ("it's not clear to me that knowledge of spreads in other companies is going to be relevant either. One thing I learned from the bench trial is how specific this is company by company. Each company has a different tale"). Generalized deliberations and information about spreads on other drugs, or about flaws in the reimbursement system, or about obstacles to changing the system, are of insubstantial relevance to the government's specific allegations against Abbott.

Abbott references this Court's November 2, 2007 ruling construing the legal meaning of the term "average wholesale price," and suggests (with no basis) that the documents on the logs contradict the government's statements in its amicus brief on the issue. See *Defendant's Objections to Magistrate Judge Bowler's August 13, 2007 Order*, Docket No. 4698, at 17. Evidently, Abbott hope to use evidence obtained in discovery to re-litigate this court's interpretation of AWP in the relevant Medicare statutes. Abbott's hope has no legal basis and should be rejected. First, this Court construed the legal term "average wholesale price" in accordance with its plain meaning, which ends any interpretive exercise. *See Textron Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003). Second, even if the term "average wholesale price" was not susceptible to an interpretation consistent with its plain meaning, the documents on the logs would still be irrelevant to its construction. The documents in question reflect internal, predecisional deliberations of individual government employees. These documents do not reflect

the final decision or statement of the agency on any issue. It is well-established in the case law that when construing a statute or regulation, "agency interpretations are only relevant if they are reflected in public documents." *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). The documents on the logs reflect the informal, internal opinions of individual agency employees, and cannot, as a matter of law, be relevant to an interpretation of the term "average wholesale price." *See, e.g.,* Ex. 2, *United States ex rel. Wright v. Agip, et al.*, No. 03-CV-00264 at 7-9 (E.D. Tex. June 29, 2007) (holding that government employees' interpretation of regulatory term was irrelevant to legal construction of that term, as well as to defendant's scienter under the FCA, in the absence of evidence of communication between government employee and defendant).

The Government's case against Abbott is a discrete one – the United States is suing Abbott for its pricing and marketing conduct with respect to a handful of drugs. Tellingly, when it comes to discovery into Abbott's conduct, Abbott takes a narrow view of the scope of the allegations in this case. For example, it has argued that with respect to discovery against Abbott or discovery directed to third parties, requests should be limited to the subject drugs and the claims period. *See, e.g.*, *Abbott's Motion for Protective Order and Motion to Quash Plaintiff' Third-party Subpoenas*, Docket No. 4293 at 3 "[t]he Government's complaint is narrowly drawn to include claims related to four drugs only – not every drug Abbott sells. And this complaint sets the metes and bounds of permissible discovery in this case . . ."). When it comes to discovery against the government, however, Abbott argues for broad discovery completely untethered to the subject drugs, its conduct, or any legally supportable defenses that it may have in this case.

In sum, Abbott does not want this case to be about its conduct. Abbott wants this case to be about pillorying the government for maintaining what it views as a flawed set of reimbursement systems for prescription drugs. Abbott's defense is premised upon the notion that the government's failure to change its reimbursement systems, despite governmental awareness of flaws, gave Abbott a license to abuse those systems. To bolster this putative defense, Abbott asks for every document in the government's possession reflecting knowledge of spreads on drugs, presumably so that it can argue that the government's continued use of an AWP-based pricing benchmark amounted to acquiescence in Abbott's theft. The problem for Abbott is that the argument that the Government should have upended its entire method of reimbursing drugs because of Abbott's misconduct is simply not a defense to the specific causes of action that the United States has brought against Abbott. Abbott wants to make this case about the system, not about its conduct, because Abbott's conduct is fundamentally indefensible. The Court should not countenance Abbott's efforts, and certainly should not vitiate a significant governmental privilege to assist Abbott in building a legally insupportable defense.

II. The United States Has Not Waived Its Right to Assert the Deliberative Process Privilege by Bringing this Case, and the Balancing Test Tips Heavily in the Government's Favor

Abbott's contention that the United States has comprehensively waived its deliberative process privilege by intervening in the instant case against Abbott is unsupportable in the extant case law. As was discussed in Section I, *infra*, the United States' allegations in the instant case do not place at issue the subject matter of any of the deliberations contained on its privilege logs at issue, and a wholesale waiver in such circumstances would be unprecedented. Courts have consistently rejected the argument that the deliberative process privilege is waived simply

because the government is a plaintiff in an enforcement action. *See Landry v. FDIC*, 204 F.3d 1125, 1136 (D.C. Cir. 2000); *United States v. Hooker Chemicals and Plastics*, 114 F.R.D. 100, 103 (W.D.N.Y. 1987). Typical circumstances in which courts have found a blanket waiver of the privilege have been in circumstances where the governmental entity's subjective motivations were *the* issue in the litigation, such as in a Title VII context. *See In re Subpoena Duces Tecum Served on the Comptroller of the Treasury,* 145 F.3d 1422, 1425 (D.C. Cir. 1998) (privilege must give way when issues in case make deliberative processes the issue in dispute, as in Title VII discrimination cases).[1] As described in Section I, *infra*, the allegations in the United States' complaint involve no such issue; this case is about Abbott's conduct, not about the United States' subjective motivations, and wholesale waiver would thus be unsupportable in the case law.

The United States acknowledges that the deliberative process privilege is not absolute. After concluding that the privilege has been properly invoked, the court must balance the public interest in protection of the deliberative process against the particularized need for the information as evidence in the case before it. In its own objections to the Magistrate Judge's

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[1] Abbott cites several additional cases for the proposition that "wholesale waiver" of the deliberative process privilege is appropriate anytime the government is a plaintiff, all distinguishable from the instant case. In *Ghana Supply Commission v. New England Power Co.*, 83 F.R.D. 586 (D. Mass. 1979), the Court held that the Ghanian government waived its right to assert a deliberative process privilege over certain documents and highly relevant to New England Power's defense in a conversion case; the court noted that the documents at issue "go to the very heart of the relationship of [the parties], a relationship that is central to [defendant's] defense that it was a bona fide purchaser in good faith . . . ." *Id.* at 590. In *Dep't of Econ. Development v. Arthur Anderson Co.* 139 F.R.D. 295, 298-99 (S.D.N.Y. 1991), the court reviewed the documents at issue *in camera,* and actually applied the balancing test to the documents before ordering their disclosure, as opposed to relying on a holding of wholesale waiver. In both cases, the documents at issue were of critical relevance to the defendant's specific defenses to the allegations at issue, unlike the documents defendant seeks in the instant case.

April 13, 2007 order, the United States set forth the oft-cited articulation of the relevant "balancing test" in *In re Franklin Nat'l Bank Sec. Litig.*, 478 F.Supp 577, 583 (E.D.N.Y. 1979), which requires courts to weigh:

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

Abbott incorrectly applies this test to the documents on the logs. First, as set forth in Section I, *infra*, these documents are of little to no relevance to the relevant issues in this case. A party cannot, as a matter of law, demonstrate "need" in the absence of relevance, and the relevance of the privileged documents here is at best minimal. *See United States v. Farley*, 11 F.3d 1385, 1390 (7th Cir. 1993). Abbott cannot and does not argue that these non-public documents are somehow relevant to its *scienter*, and Abbott does not show that any of these documents are pertinent to issues concerning materiality, causation, or the United States' reliance on Abbott's reported prices in reimbursing Abbott's subject drugs.

An appropriate application of the second prong of the balancing test, the "availability of other evidence," is especially telling in this context. Abbott claims to want to know what individuals within the government knew, understood, and believed about AWP-based reimbursement systems. In its Objections, Abbott cites the deposition testimony of former CMS Administrators Bruce Vladek and Thomas Scully, in which these witnesses make the wholly unremarkable point that individual government officials were aware of AWPs exceeding acquisition costs in some instances, and found the AWP-based reimbursement systems difficult to change because of political and legal constraints. *See Defendant's Objections to Magistrate Judge Bowler's August 13, 2007 Order* at 13. Abbott argues that this kind of testimony will

never reach the jury under the government's theory of relevance. Setting aside the question of whether this sort of "evidence" would ever reach the jury, the fact is that Abbott was able to obtain this kind of information from live witnesses without invading a privilege. Abbott has taken numerous depositions of various CMS and OIG officials, and asked them repeatedly what they knew, understood, or believed about AWP-based reimbursement systems – and those sorts of questions in depositions have *not* brought instructions not to answer on privilege grounds. Tellingly, Abbott has not asked any of these witnesses whether they knew of or approved of Abbott's specific pricing or marketing conduct. Regardless, Abbott has been able to obtain a substantial quantum of information regarding what government officials knew and understood about drug reimbursement generally, and there is no reason to vitiate a privilege to obtain other iterations of this information.

The privilege, in this case, is being applied very narrowly to a discrete set of documents reflecting predecisional and deliberative events. The volume of documents on the logs is entirely a function of the enormous breadth of Abbott's document requests. For example, Abbott's RFP No. 126 asked the United States to produce all documents withheld from the United States' response to two broad subpoenas the United States received in 2003 in this and another MDL pending in this district. In response to these subpoenas, the United States produced well over 100,000 pages of documents, documents that were disclosed to Abbott in the instant case as part of the United States' initial disclosures. The United States ultimately withheld 451 documents from this massive production. With respect to the OIG log, as was articulated in its own objections to the August 13, 2007 order, the United States has produced a substantial body of OIG documents, including the final reports, CMS's comments on the final reports, the underlying

facts and data upon which the report was based, data collection instruments, and non-deliberative internal OIG communications. What has been withheld on the OIG side is a limited number of documents, consisting primarily of internal drafts of the final reports and deliberative communications between OIG and CMS officials prior to the finalization of CMS' comments. The government's privilege assertions in the instant case have been narrow – the size of the logs is the result of Abbott's broad discovery requests. *See, e.g*, Ex. 3, *Abbott's First set of Requests for Production*, at 13-14, RFPs 19-21 Schedule A (seeking all documents relating to broad set of OIG audits and analyses).

The United States' position on prongs three through five of the relevant balancing test have been set forth in other briefs, and need not be reiterated here. However, one of Abbott's arguments with respect to the fifth prong, namely, the potential chilling effect upon the government if the documents are released, is worthy of some comment. The United States submitted declarations from Robert A. Vito, a Regional Inspector General, and the then-Acting Administrator of CMS, Leslie V. Norwalk, setting forth the categories of documents sought to be protected and the importance of protecting those documents in the advancement of their respective agencies' missions. Abbott dismisses the declarations of these senior agency officials, arguing that they do not articulate the harm that would come from disclosure with the necessary degree of specificity. It is unclear from their papers exactly what it is Abbott believes the declarations need contain to be acceptable. Abbott's broad document requests have captured a number of privileged documents. Given the breadth of Abbott's document requests, it would be exceptionally burdensome for the United States to have a senior agency official go through each document on the logs and articulate some specific harm that would come from the release of that

document. Furthermore, such a document-by-document analysis is unnecessary. The agency officials are familiar with the deliberative communications reflected in the documents on the logs, and have articulated the harm to their agencies' missions that would come from the compromise of those processes. Nothing more is required, and Abbott's demands for greater specificity are best viewed as a backdoor attempt to bar the United States from asserting the privilege in this case, by making the assertion of the privilege so burdensome as to be impossible. Such an effort should be rejected by this Court.

III. Abbott's Objections, if Sustained, Would Have a Chilling Effect on Future Fraud Litigation

The relief Abbott seeks would, if granted, have an effect far beyond the specific result in this case. While this Court is doubtless suspicious of arguments premised upon a "parade of horribles," this is one of the rare instances where such an argument is persuasive. If Abbott's arguments are adopted, they would have a substantial effect upon future litigation, and that effect would be deleterious to the United States' ability to recover monies fraudulently obtained.

First, Abbott's argument that the United States "waived' the deliberative process privilege by bringing an affirmative case against Abbott would have a significant chilling effect upon future litigation. The deliberative process privilege is an "ancient privilege [that] is predicated on the recognition that the quality of administrative decision making would be undermined if agencies were forced to operate in a fishbowl." *Dow Jones & Co., Inc. v. Department of Justice*, 917 F.2d 571, 573 (D.C. Cir. 1990) (internal quotation marks and citation omitted). Candid, internal agency discussions are instrumental to effective government. Federal administrative agencies have a direct interest in pursuing the recovery of funds lost through fraud. However, if such recovery efforts necessitate the waiver of *all* of their deliberative

processes, agencies will be in the untenable position of having to choose between protecting the fiscal integrity of their programs and the internal communications necessary to manage those programs effectively. In some circumstances, the deliberative process privilege must give way because the substance of a particular deliberative communication lies at the heart of the relevant issues in a case. That situation simply does not exist in most FCA cases, where the focus is on the defendant's conduct and scienter, and it certainly does not apply here. We have been unable to locate a single case where the deliberative process privilege was waived simply because the government brought an FCA case. Abbott's request that this Court do so would break new ground in a legally insupportable way.

Second, Abbott's view of relevance in the FCA context is itself deeply troubling. Abbott's argument is that the privileged documents shed light on government awareness of spreads and systemic problems with AWP-based reimbursement. Abbott's objections are replete with references to its need to develop evidence about "why CMS continued to use published drug prices," as it argues that such evidence is critical to its defense. *Defendant's Objections to Magistrate Judge Bowler's August 13, 2007 Order*, Docket No. 4698 at 18.

Abbott, of course, has plenty of such "evidence" from the public record and from its discovery of non-deliberative materials, and need not vitiate an important governmental privilege to obtain such information at the discovery stage. More troubling, Abbott appears to want to argue that the United States' failure to scrap its entire drug reimbursement system is somehow a defense to Abbott's conduct in violation of the FCA. This argument has major ramifications for future fraud litigation. The government is constantly in the process of evaluating its systems and policies for disbursing public funds, whether those expenditures be through procurement

policies, grant and loan programs, or reimbursement systems for health care goods and services. It is indisputable that many Government disbursement systems are subject to abuse. It is not a defense to an FCA claim, however, to say that the Government's failure to change a system subject to abuse permits a defendant to abuse that system. If such an argument is a defense, then the Government is going to have significant problems in bringing cases to recover fraudulently secured funds in the future. Of course, Abbott is free to argue that it believed that reporting one thousand percent spreads was acceptable under the system as it existed – but the focus in such a circumstance will be on Abbott's scienter, and not on the government's policy choices.

CONCLUSION

For the foregoing reasons, Abbott's Objections to the August 13, 2007 Order of Magistrate Judge Bowler should be denied.

Respectfully submitted,

For the United States of America,

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Dated: September 17, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "UNITED STATES' RESPONSE TO DEFENDANT ABBOTT LABORATORIES INC.'S OBJECTIONS TO AUGUST 13, 2007 ORDER BY MAGISTRATE JUDGE BOWLER" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ John K. Neal
John K. Neal

Dated: September 17, 2007